

CITIZENS PETITION

TO:

FDA- Dockets Management Branch (HFA-305)
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

4554 '99 APR -7 AIC :12

RE: [Docket No. 98N-0044] RIN 0910-AA59 Regulations on
Statements Made for Dietary Supplements Concerning the Effect of
the Product on the Structure or Function of the Body; Proposed Rule
and Dietary Supplements: Comments on Report of the Commission
on Dietary Supplement Labels; Notice

Please be advised that I vehemently oppose the proposed restrictions
on the dissemination of medical information as it relates to dietary
supplement health claims for the following reasons:

1. I need this information to determine what supplements I should take and which supplements I should avoid. Your restriction on the types of claims that can be made will adversely effect my health, and the health of the millions of Americans who rely on the dissemination of specific medical information relating to disease states in order to determine which dietary supplements to take.
2. Your proposed rules are in violation of the free speech provisions enumerated in the First Amendment to the United States Constitution.
3. Your proposed rules are contrary to a Supreme Court decision on June 28, 1993. The Commission on Dietary Supplement Labels (whose advice you were following when you drafted your proposed rule) defied the Supreme Court Decision of Daubert v. Merrill Dow. (I hereby put you on notice that the FDA is required to abide by Supreme Court decisions when proposing new regulations.)
4. In your proposed rule, you say that it would be illegal to suggest anything but drugs to reduce nausea associated with chemotherapy. This is arbitrary and capricious. What about nutrients such as ginger that have been shown to reduce nausea? What about coenzyme Q10 and vitamin E to reduce chemotherapy-induced cardiomyopathies, melatonin to reduce chemotherapy-induced immune system damage, and N-acetylcysteine to reduce chemotherapy induced liver damage? Are cancer patients to be denied this information?

Because your proposed rule is of questionable legality in view of the Daubert decision, and will cause many Americans to suffer and die, I hereby call for its immediate withdrawal.

Signed: G. Mackellen

C 22301

Date: 3/30/99

Address: 319 Nickerson #203

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CC: To my U.S. representative and two senators